

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

HOSPIRA, INC.

Plaintiff,

SANDOZ, INC.,

Intervenor-Plaintiff,

v.

SYLVIA MATHEWS BURWELL,
SECRETARY U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES,

DR. MARGARET HAMBURG,
COMMISSIONER U.S. FOOD AND DRUG
ADMINISTRATION,

Defendants,

MYLAN INSTITUTIONAL LLC,

PAR STERILE PRODUCTS, LLC,

Intervenor-Defendants.

Case No. 8:14-cv-02662-GJH

**INTERVENOR-DEFENDANT PAR STERILE PRODUCTS, LLC's
MEMORANDUM IN OPPOSITION TO HOSPIRA'S MOTION FOR SUMMARY
JUDGMENT AND ITS MOTION FOR A PRELIMINARY INJUNCTION**

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This is an APA case; the administrative record is closed; and the FDA's decision, viewed under the deferential Administrative Procedure Act ("APA"), cannot be characterized as "arbitrary and capricious."

To decide this case on the merits, this Court need only answer two questions:

➤ Was the FDA's interpretation of the Federal Food, Drug & Cosmetic Act ("FDCA") contrary to law? *See* 5 U.S.C. § 706(2)(A). Hospira, Inc. ("Hospira") incorrectly posits that the FDCA unequivocally and specifically speaks to the approval of generic drug labels in the context of a fictional overlap with Hospira's patent use code, and therefore, the FDA's interpretation contradicts the FDCA under Step One of the *Chevron* doctrine. *See Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). The FDA disagrees, and Par disagrees. The plain language of the FDCA states that section viii carve-outs should be approved after a generic applicant provides a statement identifying a method of use patent and indicating that the patent does not claim a use for which the generic applicant is seeking approval. 21 U.S.C. § 355(j)(2)(A)(viii). The plain language of the FDCA provides the FDA broad authority to work out the details on a case-by-case basis, and the FDA's interpretation of the FDCA is entitled to *Chevron* deference. The FDA's interpretation cannot reasonably be characterized as contradicting the FDCA or any existing rules and regulations.

➤ Was the FDA's decision to approve Par Sterile Products, LLC's ("Par") ANDA arbitrary or capricious? The inquiry is restricted to whether the FDA seriously blundered, e.g., allowing a company to ship misbranded and unapproved drug products into the United States. *Beatty v. FDA*, 853 F. Supp. 2d 30, 37 (D.D.C. 2014) (finding the FDA's decision to be arbitrary, capricious, and contrary to law). Hospira cannot, by sheer force of will, seriously call into question the well-thought-out August 18, 2014 decision of the FDA in this particular case.

Despite the simplicity of this case, Hospira tries to derail the analysis by introducing red-herrings and straw-man arguments. For example, Hospira's argument that the FDA's decision veered so far from typical FDA decision-making that it constitutes "rule-making" under the APA is a blatant red-herring. The FDA created no new rule, and the FDA's August 18, 2014 decision is specifically directed to Par and Mylan's ANDAs.

Hospira's whole "overlap" argument is a straw-man. The word "overlap" does not appear in the FDCA and does not appear in the FDA's rules and regulations. The word "overlap" first appears in the context of the District Court of the District of Columbia's decision in *Purepac*, where the court affirmatively noted that, if there is not overlap between a generic label and a patent use code, the ANDA should be approved. *Purepac Pharm., Co. v. Thompson*, 238 F. Supp. 2d 191, 207 (D.D.C. 2002), *aff'd*, 354 F.3d 877 (D.C. Cir. 2004). Pointing to the Solicitor General's amicus brief and the Supreme Court's dicta in *Caraco*, Hospira twists the *Purepac* court's statement into the negative proposition that an ANDA should not be approved if there is any overlap at all; and then, even though such statements are not binding on the FDA, Hospira desperately attempts to manufacture overlap in this particular case. *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). Hospira's argument is clever, but completely wrong. The statements in the *Purepac* decision, the dicta in the *Caraco* decision, and the amicus brief are not controlling. The FDA never acknowledged meaningful overlap between Par's label and Hospira's manipulated use code in its decision, and the FDA concluded that Hospira's use code provides sufficient space for Par's label. No one cares about "overlap"—except Hospira—because it is irrelevant to deciding this case.

For the reasons explained in Par's opposition to Hospira's motion for a preliminary injunction and Par's motion for summary judgment (D.I. 97, 98), Hospira's request for a preliminary injunction should be denied. Even if the Court found one or more of the preliminary

injunction factors favoring Hospira—which Par disputes—the Court must specifically reaffirm its finding that Hospira would suffer irreparable harm in order to sanction Hospira’s circumvention of its exhaustion requirements under the APA. The Court made its decision on the temporary restraining order (D.I. 19, 20) before defendants had a chance to contradict Hospira’s self-serving presentation of facts. Now that Par has completed the picture by submitting declarations and expert opinions of economists, Par respectfully requests the Court reconsider any finding that Hospira could be irreparably harmed.

ARGUMENT

In approving Par’s ANDA, the FDA did two things: (1) it interpreted the applicable statute and regulations—under which the FDA is accorded *Chevron* deference; and (2) it applied its interpretation of the law to the facts in the administrative record—which is reviewed under the arbitrary and capricious standard. This standard is highly deferential to the agency. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). Indeed, the agency’s administrative decision is entitled to a presumption of validity. *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743 (1985); *Camp v. Pitts*, 411 U.S. 138, 142 (1973).

I. THE FDA CORRECTLY INTERPRETED THE FDCA AS PROVIDING BROAD AUTHORITY TO APPROVE PAR’S ANDA

When Congress enacted the Hatch–Waxman Act in 1984, it included the provision for section viii carve-outs. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1585 (codified as amended at 21 U.S.C. § 355(j)(2)(A)(viii)). Section viii furthers the purpose of the Hatch–Waxman Act, which is to get less expensive drugs to the public—fast.

The section viii process is a key feature of the Hatch–Waxman generic approval framework, designed to enable ANDA applicants, in cases where an approved use of the [listed drug] is not covered by a brand company patent, to obtain immediate FDA approval for that unpatented use and to

circumvent costly, prolonged Paragraph IV litigation that would delay generic competition for years.

Br. of Rep. Henry A. Waxman as *Amicus Curiae* in Support of Petitioners, *Caraco Pharm.*

Labs., Ltd. v. Novo Nordisk A/S, 132 S. Ct. 1670 (2012) (No. 10-844), 2011 WL 3947565, at *12 (Sept. 6, 2011) (“Waxman Amicus Br.”).

A. Hospira’s Argument That the FDA’s Interpretation Fails at *Chevron* Step One Is Incorrect Because the FDCA Does Not Say Anything Regarding Use Codes, Much Less Overlaps with Use Codes

The Supreme Court’s decision in *Chevron*, set forth a two-step framework for reviewing an administrative agency’s interpretation of its statute. 467 U.S. 837 (1984). Under *Chevron* Step One: “First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.” *Id.* at 842–43. *Chevron* Step Two applies when Congress has not directly addressed the issue or has done so ambiguously. In that event, the Court may not “simply impose its own construction on the statute,” but rather must determine whether the agency’s construction is based on a permissible interpretation of the statute. *See id.* at 843, 843–44 & n.11.

1. Hospira Tries to Turn Congress’s Silence Into Support For Its Interpretation of the FDCA

Hospira argues that the FDA should not be accorded *Chevron* deference because the FDCA unambiguously expresses Congress’s intent. (D.I. 101-1 at 13.) Yet the FDCA says nothing about “overlapping” labels and “patent use codes.” Hospira is wrong, and *Chevron* Step Two applies here.

The statutory text of the Hatch–Waxman Act states that:

if [patent] information was filed . . . for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, [the ANDA applicant may file] **a statement that the method of use patent does not claim such a use.**

21 U.S.C. § 355(j)(2)(A)(viii) (emphasis added). The statutory text is silent regarding how the FDA should decide the adequacy of an ANDA applicant's statement under section viii. Nor does the text say anything about "use codes" or "overlapping" labeling. Thus, a simple reading of the statute indicates that Congress has not directly spoken to this precise issue. *See Chevron*, 467 U.S. at 842. Because Congress did not directly speak to this precise issue, *Chevron* Step Two applies, and the FDA's interpretations of the statute are entitled to deference. (Federal Def. Br., D.I. 92-1 at 23 (citing *Barnhart v. Walton*, 535 U.S. 212, 218 (2002).))

In spite of this statutory silence, Hospira interprets the FDCA as requiring that "section viii is available if, but only if, there is no *overlap* between Hospira's *use code* and the ANDA applicant's proposed use." (D.I. 101-1 at 18 (emphasis added).) But Hospira ignores the text of the statute. While the FDCA requires a brand to submit in its NDA "the patent number and the expiration date of any patent which claims the drug for which the [brand] submitted the [NDA] or which claims a method of using such drug," it does not require or define a "use code." 21 U.S.C. § 355(b)(1). Only the FDA's *implementing regulations* require that, once an NDA is approved, the brand provide a "description" of any method-of-use patent it holds. *See* 21 C.F.R. §§ 314.53(c)(2)(ii)(P)(3), (e). The brand submits that description in FDA Form 3542, which introduces the term "use code."¹ *See Caraco Pharm.*, 132 S. Ct. at 1676. Because the concept of a "use code" was created by the FDA through its implementing regulations and have no explicit statutory basis, Hospira's argument that the FDCA *itself* expressly precludes "overlap" between generic labels and "use codes" fails.

¹ As an example, Hospira submitted FDA Form 3542 for Precedex. (AR 822–25.)

2. Hospira's Cited Cases Do Not Support Its Argument that *Chevron* Step One Applies Here

Hospira cites a number of cases for the proposition that courts previously found “the language of section viii . . . quite clear.” (D.I. 101-1 at 15–16.) None of these cases, however, present the issue of whether the language of section viii is unambiguously clear regarding the FDA’s discretion to approve ANDAs. In other words, none of these cases support Hospira’s argument that *Chevron* Step One applies here.

Hospira relies especially on the district court’s decision in *Purepac*, citing it twice. But *Purepac* does not support Hospira’s *Chevron* Step One theory. The court in *Purepac* discusses section viii and affirmatively states that the carve-out is available under certain circumstances. *Purepac*, 238 F. Supp. 2d at 207. But the *Purepac* court did *not* address the question here: whether the statute speaks to the FDA’s role in “evaluat[ing] what portions of labeling appropriately correspond to the use code provided and whether ANDAs may be approvable with labeling that carves out protected information that corresponds to the use code provided.” (AR 811.) At most, the court in *Purepac* noted that the statute was clear insofar as the statute requires ANDA applicants to provide a section viii statement of inapplicable use. *Purepac*, 238 F. Supp. 2d at 207 (citing 21 U.S.C. § 355(j)(2)(A)(viii)). *Purepac* is inapposite.

The other cases cited by Hospira merely stand for the proposition that an NDA holder has no standing to sue an ANDA applicant who has submitted a section viii statement before the actual sale of the generic drug.² See *Bayer Schera Pharma AG v. Sandoz, Inc.*, 741 F. Supp. 2d 541, 553 (S.D.N.Y. 2010) (“Defendants are entitled to judgment on the pleadings concerning

² Under Section 271(e), an NDA holder can sue an ANDA applicant who has submitted a P.IV certification because the P.IV certification is a constructive act of infringement. A section viii statement is not a constructive act of infringement, and therefore, the NDA holder must wait until the generic drug is sold before suing the ANDA applicant. Here, Hospira had no jurisdiction to sue Par based on its ANDA until Par sold its product on August 19, 2014.

Bayer's patent infringement claims asserted under 35 U.S.C. § 271(e)(2)(A).”), *aff’d sub nom. Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316 (Fed. Cir. 2012); *Astrazeneca Pharms. LP v. Apotex Corp.*, No. CIV 10-338 RBK/KW, 2010 WL 5376310, *10–14 (D. Del. Dec. 22, 2010) (“Thus, Plaintiffs do not have a claim under Section 271(e)(2) and this Court does not have jurisdiction over this matter.”). Like *Purepac*, these cases are inapposite, as they do not deal with the issue in this case.

3. Under *Chevron* Step Two the FDA’s Decision Is Permissible

Under *Chevron* Step Two, “[t]he FDCA confers broad authority to the FDA to approve generic drugs that omit information protected by a method-of-use patent.” (Federal Def. Br., D.I. 92-1 at 21.) The sole inquiry is whether the FDA’s construction of the FDCA was based on a *permissible interpretation* of the statute. *See Chevron*, 467 U.S. at 843, 843–44 & n.11.³ Importantly, the Court cannot “simply impose its own construction on the statute.” *Id.* at 843.

The FDA implements section viii through Rule 94, which lays out the “content and format of an [ANDA].” 21 C.F.R. § 314.94 states (in pertinent part):

[ANDAs] are required to be submitted in the form and contain the information required under this section.

(a)(12) Patent certification—

* * *

(iii) Method of use patent.

(A) If patent information is submitted under section 505(b) or (c) of the act and 314.53 for a patent claiming a method of using the listed drug, and the labeling for the drug product for which the applicant is seeking approval does not include any indications that are covered by the use

³ In case of statutory ambiguity, the Court must uphold the agency’s interpretation if its construction is permissible under the statute. *See Barnhart v. Walton*, 535 U.S. 212, 218 (2002) (holding that the reviewing court must decide: (1) whether the statute unambiguously forbids agency interpretation; and (2) whether the agency interpretation exceeds the bounds of the permissible).

patent, a statement explaining that the method of use patent does not claim any of the proposed indications.

21 C.F.R. § 314.94(a)(12)(iii)(A); *see also* § 314.94(a)(8)(iv) (labeling requirements).⁴

According to this rule, because Hospira listed a method-of-use patent (e.g., the '867 patent) and the labeling of Par's product does not include any indications covered by the patent, Par submitted "a statement explaining that the method of use patent does not claim any of the proposed indications." 21 C.F.R. § 314.94(a)(12)(iii)(A). To the extent the FDA interpreted its own regulations in approving Par's ANDA, the FDA's interpretation is entitled to "substantial deference." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994); *see Fed. Express Corp. v. Holowecki*, 552 U.S. 389, 397 (2008) (stating that courts accept an agency's interpretation of its regulations unless the agency's position is "plainly erroneous or inconsistent with the regulation" (internal quotation marks omitted)). Hospira does not argue otherwise.

4. Courts Have Routinely Extended *Chevron* Step Two Deference to The FDA

Chevron Step Two deference extends to administrative determinations that are not embodied in rulemaking or formal adjudication. *Barnhart*, 535 U.S. at 221–22. In *Mylan Laboratories, Inc. v. Thompson*, for example, the D.C. Circuit extended *Chevron* Step Two deference to the FDA's interpretation of ANDA exclusivity provisions expressed in a letter decision. The court explained that deference was appropriate because of "the complexity of the statutory regime . . . the [presence of] FDA's expertise or the careful craft of the scheme it devised to reconcile the various statutory provisions." *Mylan Labs., Inc. v. Thompson*, 389 F.3d 1272, 1279–80 (D.C. Cir. 2004); *see also Novartis Pharms. Corp. v. Leavitt*, 435 F.3d 344, 351–

⁴ 21 C.F.R. § 314.92(a)(1) states that a proposed generic product must have the same conditions of use as the listed drug, except that "conditions of use for which approval cannot be granted because . . . an existing patent may be omitted." This rule clarifies that the required conditions of use may be carved-out for patent purposes.

52 (D.C. Cir. 2006) (deferring to FDA’s interpretation of a statute without notice-and-comment rulemaking).

In this case, the FDA permissibly interpreted the FDCA and its regulations to approve Par’s product. FDA interpreted the FDCA and its regulations as permitting FDA to “approve ANDAs for broad, general indications that may partially overlap with a protected method of use, so long as any express references to the protected use are omitted from the labeling.” (AR 813.) Thus, it was fully consistent with the FDCA to approve Par’s ANDA because Par’s proposed labeling completely carves-out any mention of the protected method of use. (*See* AR 1002–28.) Further, the FDA noted that this interpretation is consistent with its prior interpretations and its past practice. (*Id.*) This interpretation of the complex, technical, scientific scheme is permissible—Hospira does not even advance an argument under *Chevron* Step Two. (*See* D.I. 101-1 at 17–21.)

The answer to the first question before the Court is clear: The FDA’s interpretation of the FDCA and its own regulations is subject to *Chevron* Step Two deference. Hospira’s argument that *Chevron* Step One applies because the FDCA is unambiguously clear regarding how FDA should handle the “overlap” between “use codes” and product labeling is meritless—the statute mentions neither “overlap” nor “use codes.” Under *Chevron* Step Two, the FDA’s interpretation is entirely reasonable and within permissible bounds.

B. The *Caraco* Dicta Is Not Relevant To This Case

Implicitly acknowledging that the FDCA does not mention “overlap” or “use codes,” Hospira argues that the Supreme Court’s decision in *Caraco* (rather than Congress) “has directly spoken to the precise question at issue.” (D.I. 101-1 at 13 (quoting *Chevron*, 467 U.S. at 842).) Hospira’s reliance on *Caraco* fails.

1. Caraco Does Not Support Hospira's Argument That *Chevron* Step One Deference Applies Here

In *Caraco*, the generic applicant (Caraco) sought approval to market a generic version of one of Novo Nordisk's ("Novo") products. Caraco sought to carve out one of three approved indications for the product under section viii. *Caraco*, 132 S. Ct. at 1678–79. To obstruct Caraco's section viii carve-out, Novo broadened its use code in the hope of covering Caraco's proposed indication. Caraco, who was already in a lawsuit with Novo for another patent, filed a counterclaim in that case seeking an order requiring Novo to correct its use code because it was overly broad. The district court granted Caraco summary judgment and ordered Novo to correct its use code. *Id.* at 1679. The Federal Circuit reversed, holding that the district court had no jurisdictional basis for hearing the counterclaim. *Id.* at 1679–80 (quoting the opinion below). The Supreme Court granted certiorari and reversed, holding that the counterclaim was, indeed, available to challenge the accuracy of use codes. *Id.* at 1687.

The facts and holding in *Caraco* do not support Hospira's *Chevron* Step One argument. The only common elements between *Caraco* and the present case is that both cases involve manipulation of use codes to block the FDA's approval of the ANDA. The question was purely jurisdictional: whether the district court had the capacity to hear Caraco's counterclaim.⁵ *Caraco* is inapposite to the case here.

2. The Statement upon which Hospira Relies Is Admittedly Dicta

Hospira admits that its *Chevron* Step One argument is based on dicta in *Caraco*. (D.I. 101-1 at 15.) Indeed, the supposed authority on which Hospira relies is in the background section of the Court's opinion, where the Court merely provides an overview of the Hatch–

⁵ The holding of *Caraco* is the following: “We cannot say that the **counterclaim clause** is altogether free of ambiguity. But when we consider statutory text and context together, we conclude that a generic manufacturer in Caraco's position can **use the counterclaim.**” *Caraco*, 132 S. Ct. at 1680 (emphasis added).

Waxman statutory scheme. To the extent Hospira insists that the Supreme Court’s background statements control with respect to whether an ANDA is approvable when the label and use code “overlap,” Hospira does not explain why *another* Supreme Court statement in the same paragraph, noting that an ANDA may be approved if there is “sufficient space for the generic’s proposed label,” is also not controlling. *See Caraco*, 132 S.Ct. at 1677. Hospira is cherry-picking.

Essentially, Hospira argues that the Supreme Court’s background statements in *Caraco* created binding precedent applicable to the *Chevron* Step One inquiry. Hospira’s position is contrary to the law and common sense. Dictum is “[a] judicial comment made during the course of delivering a judicial opinion, but one that is unnecessary to the decision in the case and therefore not precedential (though it may be considered persuasive).” Black’s Law Dictionary 1100 (7th ed. 1999) (defining “obiter dictum”). Dicta, even Supreme Court dicta, cannot trump an agency construction—only the court’s *holding* controls:

A court’s prior judicial construction of a statute trumps an agency construction otherwise entitled to *Chevron* deference **only if the prior court decision holds that its construction follows from the unambiguous terms of the statute and thus leaves no room for agency discretion.**

Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Servs., 545 U.S. 967, 982 (2005) (emphases added); *cf. Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 379 (1994) (“It is to the holdings of our cases, rather than their dicta, that we must attend . . .”).

Hospira cannot ignore the statute and rely on dicta in *Caraco* to make its *Chevron* Step One argument. *Caraco* did not hold that “the unambiguous terms” of section viii “leaves no room for agency discretion.” *Brand X*, 545 U.S. at 982. Thus, as the FDA explained in its decision (AR 813–16), *Caraco* is inapposite and irrelevant.

II. THE “ARBITRARY AND CAPRICIOUS” STANDARD APPLIES TO THE FDA’S APPLICATION OF LAW TO FACTS IN THE ADMINISTRATIVE RECORD

Hospira’s complaint and motion for summary judgment challenges the FDA’s decision to approve Par and Mylan’s ANDAs. The FDA’s decisions are presumptively valid. *Fla. Power & Light*, 470 U.S. at 743; *Camp*, 411 U.S. at 142. To prevail, the burden is on Hospira to prove that the FDA’s decision was “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). An “arbitrary and capricious” decision means:

[T]he agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43, (1983).

The FDA’s decision to approve Par’s ANDA easily meets the arbitrary and capricious standard. The decision is a result of the FDA’s reasoned consideration of the law and facts, from the viewpoint of its scientific expertise. Because its decision involves technical and scientific issues of product labeling and drug safety, its decision is entitled to considerable deference. *See, e.g., Ethyl Corp. v. EPA*, 541 F.2d 1, 36 (D.C. Cir. 1976). Acknowledging this, Hospira advances no argument specifically attacking the FDA’s decision as arbitrary and capricious—it only posits that FDA’s decision should not be accorded *Chevron* deference and is contrary to law. (*See* D.I. 101-1 at 18–19.)

This is not, however, a case where the FDA completely blundered. *See, e.g., Beaty*, 853 F. Supp. 2d at 41–43 (holding that the FDA incorrectly allowed Beaty to ship misbranded and unapproved product into the United States). The FDA’s decision is reasoned and consistent with its prior decisions and its regulations. (AR 813–16.)

A. Hospira's Amended Use Code, the Public Docket, and the FDA's Review of the Par's Carve-Out

Hospira amended its use code on January 6, 2014 (AR 859–63), and requested the FDA not to approve Par and Mylan's section viii statements. (AR 858.) The FDA accepted the amended use code and updated the Orange Book accordingly. (AR 901.) The FDA then notified Hospira that its proper course of action to challenge FDA approval of a generic application was to submit a citizen petition so that interested parties could publically comment. (AR 864–65 (citing 21 U.S.C. § 355(q))).) Hospira neither filed a petition nor withdrew its request that the FDA refuse to approve Par and Mylan's ANDAs.

Because Hospira's request potentially prejudiced Par, Mylan, and other P.IV applicants seeking approval to market generic Precedex, the FDA opened a public docket to solicit comments on three issues created by Hospira's use code change. (AR 1–3.)

In the public docket, the FDA received numerous comments, including comments from Hospira (AR 88–230, 555–64), Sandoz (AR 54–60, 580–85), Mylan, JHP Pharmaceuticals (Par) (AR 231–542, 592–794), and other pharmaceutical companies and organizations. The various comments argued for or against the FDA's approval for different reasons. (*See* AR 811.) The FDA considered the opinion of its technical staff regarding the contents of the proposed carve-out labels as compared to Hospira's use code. (*See generally* AR 1055–1153.) The FDA also considered the scientific opinion of its Division of Anesthesia, Analgesia, and Addiction Products. (AR 978–95.)

B. The FDA's August 18, 2014 Decision

On August 18, 2014, after seven months of collecting and reviewing comments and evidence, the FDA issued its decision in a public letter: "FDA concludes that regardless of whether the original use code or the revised use code applies, the agency can approve an ANDA

that submits a ‘section viii’ statement and omits labeling that discloses the protected use (as identified by Hospira).” (AR 804.)

In the letter, the FDA described the Factual Background, including the issues presented (AR 805), the Legal and Regulatory Background (AR 806–11), a detailed Discussion section (AR 811–17), and a Conclusion (AR 817). In the FDA’s description of the legal and regulatory background section, the FDA articulated its understanding of the statutory framework for patent protection, for little viii carve-outs, the requirements under the Hatch–Waxman Act, and the agency’s role in technical review and expert oversight regarding generic drug labeling. (AR 806–11.)

When a patent is listed only for a method of use, an ANDA applicant seeking to omit that approved method of use covered by the listed patent need not file a paragraph III or IV certification for that patent. Instead, the applicant may submit a “section viii statement” acknowledging that a given method-of-use patent has been listed, but stating that the patent at issue does not claim a use for which the applicant seeks approval.”

(AR 808 (citing § 505(j)(2)(A)(viii)).) “Such a statement requires the ANDA applicant to omit from its labeling information pertaining to the protected use.” (AR 808 (citing 21 C.F.R. § 314.92(a)(1), § 314.94(a)(12)(iii).) The FDA notes that courts have not questioned the right of ANDA applicants to file a section viii statement. (AR 809 (citing *Purepac*, 354 F.3d at 880; *Torpharm Inc. v. Thompson*, 260 F. Supp. 2d 69, 73 (D.D.C. 2003).)

In the discussion section, the FDA addressed Hospira’s arguments.

First, the FDA clarified that Hospira was wrong when it argued that the FDA was not allowed to evaluate Par’s label when considering whether to approve its section viii statement. Although Hospira insisted that the FDA’s role was ministerial, the FDA responded that “we . . . regularly evaluate what portions of labeling appropriately correspond to the use code provided and whether ANDAs may be approvable with labeling that carves out protected information that corresponds to the use code provided. Such determinations fall squarely within the ambit of

FDA's scientific expertise." (AR 811.) After considering Hospira's use code and Par's label, the FDA determined, using its scientific expertise, that:

[I]n this instance, we can approve an ANDA that omits the information Hospira has identified as protected by the use code because we have concluded that such omissions do not render the drug less safe or effective for the remaining non-protected conditions of use.

(AR 812.) The FDA determined that Par's label makes no mention of the ICU, and according to Hospira's own use code (old or new), the protected condition of use requires sedation in the ICU.

Second, the FDA acknowledged Hospira's overlap theory. (AR 812 ("[T]here is a subset of non-intubated patients that may receive Precedex for procedural sedation (the second indication) in the ICU setting.")) The FDA decision provides a detailed rejection of Hospira's theory:

FDA previously has determined that it can approve ANDAs for broad, general indications that may partially overlap with a protected method of use, so long as any express references to the protected use are omitted from the labeling. The procedural indication and related information in the labeling do not impermissibly disclose the use of Precedex for procedures in the ICU (i.e., for the use covered by the use code).

(AR 813.) Again, Par's label makes no mention of ICU, and according to Hospira's own use code (old or new), it requires sedation in the ICU. The FDA acknowledged Hospira's reliance on the Supreme Court's dicta in *Caraco*, and observed it does not control. Again, the FDA reiterated its conclusion:

ANDAs for Precedex may carve out the protected information (related to use for ICU sedation), and be approved for procedural sedation despite the fact that use for procedural sedation may at times occur in an intensive care setting. Use in an intensive care setting is not expressly disclosed in any proposed ANDA labeling.

(AR 815.) The FDA noted that the agency had previously taken this approach. (*See* AR 813; *see also* AR 815–16 (describing tramadol and oxandrolone approvals); AR 1154–67 (tramadol decision); AR 1168–88 (oxandrolone decision).)⁶

The FDA factually distinguished the *Caraco* decision, stating that in that case, “if references to the use described in the use code were carved out, there would be no indication left to reference.” (AR 814; *see* AR 815 (“And Caraco could not carve-out those uses as well, ***because at that point nothing would be left for it to market.***” (quoting *Caraco*, 132 S. Ct. at 1679 (emphasis added)).)

Third, the FDA discussed the role of section viii within the statutory framework, and rejected Sandoz’s argument that section viii approvals undercut incentives created by other statutory provisions: “There is no [] prohibition in the statute to submitting a section viii statement and carving out an indication (in fact, the statute authorizes this), and FDA declines to infer one here.” (AR 817.)

Overall, the FDA’s decision to allow the ANDA applicants to carve-out ICU sedation was based on its technical assessment of whether the protected use, as described in the use code, was described in the generic label, and whether the carve-out labels were safe and effective. The FDA concluded that:

Use in an intensive care setting is not expressly disclosed in any proposed ANDA labeling. Hospira’s reliance on a single sentence about a different type of “overlap” at issue in *Caraco* does not control the outcome here.

(AR 815; *see* AR 817 (concluding that the ANDA applicants’ labels were safe and effective).)

⁶ In fact, the FDA decision specifically discussed the previous approval of repanglide, the drug at issue in *Caraco*. The FDA pointed out that it had initially permitted a carve-out “even though the scope of the broad indication partially overlapped in substance with the method of use described by the use code at the time” because the patented use described in the use code was not disclosed in the carved-out labeling. (AR 814; *see also* AR 1234–35 (examining whether the language of the proposed generic label actually discloses the patented use).)

C. The FDA’s Decision Is Thorough and Thoughtful; It Cannot Fairly be Portrayed as a Blunder Rising to the Level of Arbitrary or Capricious

The FDA’s decision receives deference when reviewed by this Court. Nothing in the decision constitutes a major blunder or even a deviation from past conduct. The agency provided legitimate reasons for approving Par’s ANDA despite Hospira’s argument regarding “overlap.” *See Sanofi-Aventis U.S. LLC v. FDA*, 842 F. Supp. 2d 195, 212 (D.D.C. 2012) (holding that the FDA’s decision “satisfied the minimal standard of rationality required” by providing legitimate reasons). The FDA considered the relevant factors, including Hospira’s description of its use code, Par and Mylan’s proposed labeling, the FDA’s past practice, the statutory framework, and the FDA technical staff’s conclusion that the ANDAs could be approved with the omission of sedation for the purpose of ICU treatment and would not be less safe and effective for procedural sedation. (AR 813–17.) *See Cumberland Pharm. Inc. v. FDA*, 981 F. Supp. 2d 38, 49 (D.D.C. 2013) (“The FDA’s reasoning here . . . is consistent with logic and sufficiently explained.”); *see also id.* at 48–49 (responding “point-by-point” to the arguments made in the citizen’s petition and incorporating independent analysis from the Gastroenterology Division into the decision). The agency’s reliance on its own expert and scientific judgment demonstrates sound judgment.

The FDA’s decision was rational, within the FDA’s scope and authority, reasoned, and based on permissible criteria. *See State Farm*, 463 U.S. at 43.⁷

⁷ The evidence cited by Hospira, including Dr. Friedman’s declaration (AR 177–80) and an FDA study that remarked it was “possible that there is an overlap between when people were in the ICU and when a procedure was performed” (AR 982–84) is irrelevant because the FDA based its decision on the contents of the label and the NDA’s description of its use code. *See Cumberland Pharm.*, 981 F. Supp. 2d at 49–50 (D.D.C. 2013) (rejecting the argument that some contrary evidence is enough to render a decision arbitrary and capricious).

III. CONTRARY TO HOSPIRA'S AND SANDOZ'S CONTENTIONS, FDA NEITHER ENGAGED IN RULEMAKING NOR ANNOUNCED A NEW RULE

Hospira and Sandoz launch a coordinated, multi-pronged attack essentially arguing that FDA's actions constitute rulemaking and that the subsequent August 18, 2014 decision is a rule under the APA. Both of these arguments are wrong, however, because the FDA neither engaged in rulemaking nor established a new rule. Instead, as discussed in detail below, FDA rendered its decision specifically on Par's section viii carve-out within the context of a public docket using existing FDA regulations.

A. FDA Did Not Engage in Rulemaking

Armed with the false premise that FDA engaged in rulemaking, Hospira and Sandoz unleash a series of misguided attacks complaining that FDA failed to follow the APA's mandatory procedures for obtaining prior public notice and comment prior to issuing a new rule. (Hospira Br., D.I. 101-1 at 27–28; *see* Sandoz Br., D.I. 95 at 19–20.) To borrow FDA's position, “this suggestion is preposterous.” (Federal Def. Br., D.I. 92-1 at 32.) FDA did not engage in rulemaking. Rather, FDA applied its existing regulations and determined that Par can submit a section viii statement and carve out references to ICU sedation and not be any less safe and effective than Precedex. (AR 812–13.) Thus, FDA's August 18, 2014 letter was merely a decision on the merits with respect to Par's ANDA. Indeed, that is exactly what FDA concluded when it issued its decision stating: “Today's letter reflects *FDA's determination with respect to permissibility of labeling carve outs for ANDAs referencing Precedex.*” (AR 804 (emphasis added).) *See Apotex, Inc. v. FDA*, 226 F. App'x 4 (D.C. Cir. 2007) (noting that FDA approval letters are informal adjudications).

Further, it is also well established that FDA's decision on drug approval and labeling decisions is within the purview of adjudication. “It is well within the FDA's discretion to make its labeling decisions through administrative adjudications rather than through less-formal and

less-flexible rulemaking proceedings.” *Wyeth v. Levine*, 555 U.S. 555, 623 (2009) (dissenting opinion) (citing *SEC v. Chenery Corp.*, 332 U.S. 194 (1947)). Thus, this Court should not countenance Hospira’s and Sandoz’s attempts to miscast FDA’s actions as rulemaking.

Under Hospira’s and Sandoz’s logic, FDA would need to engage in new rulemaking each time FDA interprets its existing rules and applies them to the specific facts of a particular case. Such logic is not only untenable but is impractical because requiring FDA to engage in new rulemaking each time it interprets its existing rules would materially impede FDA’s ability to approve drugs in a timely fashion, thereby delaying public access to such drugs.

Further, Hospira’s citation to a barrage of cases does not change the inevitable conclusion that this was not rulemaking. All of the cases cited by Hospira to support the notion that the FDA violated the APA are inapposite and readily distinguishable. Indeed, all of the cited cases, unlike here, involve situations where the FDA (or other regulatory agencies) issued statements of general or particular applicability that were designed to implement or prescribe law. *Syncor Int’l Corp. v. Shalala*, 127 F.3d 90, 95–96 (D.C. Cir. 1997) (announcing that PET radiopharmaceuticals “should be regulated” by the FDA under the drug provisions of the FDCA); *Cnty. Nutrition Inst. v. Young*, 818 F.2d 943, 946–49 (D.C. Cir. 1987) (FDA establishing “action levels” informing food producers of the allowable levels of unavoidable contaminants such as aflatoxins); *United States v. Articles of Drug*, 634 F. Supp. 435, 454–60 (N.D. Ill. 1985) (holding that the two FDA policies are “substantive rules of general applicability”), *vacated as moot*, 818 F.2d 569 (7th Cir. 1987); *Bellarno Int’l Ltd. v. FDA*, 678 F. Supp. 410, 413–15 (E.D.N.Y. 1988) (finding, among other things, that Import Alert # 66–14 is a new policy that requires automatic detention and re-export of all imports of AGR pharmaceuticals); *see also United States v. Bioclinical Sys., Inc.*, 666 F. Supp. 82, 83 (D. Md. 1987) (FDA insisting manufacturers of all plated culture media use a specific sterility

requirement); *N.C. Growers' Ass'n v. United Farm Workers*, 702 F.3d 755, 765–66 (4th Cir. 2012) (reinstating superseded and void Department of Labor regulations for agricultural employers); *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 241 (D.C. Cir. 2008) (promulgated rule to regulate use of radio spectrum by Access Broadband over Power Line operators); *Owner-Operators Indep. Drivers Ass'n v. Fed. Motor Carrier Safety Admin.*, 494 F.3d 188 (D.C. Cir. 2007) (petitioned for review of final rule challenging hours of service for long-haul truck drivers); *Nw. Tissue Ctr. v. Shalala*, 1 F.3d 522, 527–28 (7th Cir. 1993) (challenging FDA regulations governing replacement heart valves). Accordingly, Hospira's and Sandoz's arguments are untenable.

Sandoz and Hospira next complain that FDA's "Dear Applicant" letter initiated substantive rulemaking. (D.I. 101-1 at 9; D.I. 95 at 21.) This too is without merit. FDA's letter posted on the public docket was to allow different applicants to express their various views on the legal and regulatory issues pertaining to Precedex and to help the agency resolve these issues. (AR 1.) This is consistent with FDA's longstanding past practice in which it has opened such dockets to facilitate public consideration of issues related to generic drug approvals. *See, e.g., Actavis Elizabeth LLC v. FDA*, 689 F. Supp. 2d 174, 176 (D.D.C. 2010) ("FDA determined that the issues raised by Actavis should be considered administratively and opened a public docket . . . to receive comments from interested parties on the relevant legal and regulatory issues."), *aff'd*, 625 F.3d 760, 766 (D.C. Cir. 2010).

As a last resort, Hospira cites to the FDA's docket for Dexmedetomidine Hydrochloride Injection NDA/ANDA that categorizes the "Type" of docket as "Rulemaking." (Hospira, D.I. 101-1 at 32.) That FDA may have categorized its docket as "rulemaking" does not overcome the litany of other evidence supporting the notion that FDA merely applied its existing rules and regulations and engaged in adjudication, not rulemaking. Specifically, that the FDA did not

publish a notice of rulemaking in the Federal Register, did not provide the statutorily-required 60 days for comment, and did not publish a final regulation in the Federal Register overwhelmingly demonstrates that the FDA did not engage in rulemaking. In addition, FDA's request for,⁸ and Hospira's subsequent failure to, file a citizen petition further buttresses the fact that this was not a rulemaking but a mere adjudication.

B. FDA Did Not Issue a New Rule

In the second prong, Hospira and Sandoz both essentially complain that FDA issued a new rule by virtue of the August 18, 2014 decision.

Hospira specifically contends that FDA's "decision to authorize approval of an ANDA in the face of clear overlap between the generic's proposed carve-out label and Hospira's use code is an invalid, new, and not properly adopted rule or regulation." (D.I. 101-1 at 28–29.)

Hospira's contention is unfounded and incorrect because it conflicts with 21 U.S.C. §355(j)(2)(A)(viii), which allows applicants to obtain approvals for methods of use that are not protected by patents. Here, FDA concluded that the '867 patent's original and revised use codes are limited to "intensive care unit sedation."⁹ (AR 813.) Par's ANDA, however, was correctly approved because it omitted references to the protected use of procedural sedation in an intensive care unit. In further addressing the issue of potential overlap, FDA further reasoned that its decision is fully consistent with *Caraco* because "sufficient space exists" here in that it can approve Par's ANDA "with only the second procedural indication and related information in the labeling without disclosing the protected use." (AR 815.) In so doing, FDA merely applied the pre-existing law to the facts of this case and made an adjudication on the merits; it did not

⁸ (See AR 864–65 (requesting that Hospira "submit [its] concerns as a citizen petition in accordance with section 505(q) of the FD&C Act").)

⁹ Hospira itself conceded that the use code overlaps with procedural sedation indication but only "to the extent such sedation occurred in an ICU." (AR at 90.)

perform rulemaking or issue a new “rule” as Hospira and Sandoz mistakenly contend.¹⁰ Put differently, FDA simply interpreted language in an already existing regulation. Indeed, FDA recognized as much when it characterized the process as “decision-making” and “consistent with how FDA has implemented use codes and allowed carve outs in other circumstances.” (AR 812–13.)

Sandoz similarly argues that FDA amended a prior legislative rule. (D.I. 95 at 20.) Sandoz specifically argues that FDA’s August 18, 2004 decision amends 21 C.F.R. § 314.94(a)(12)(iii) because the “language of the indication actually approved is broader than [procedural sedation in the intensive care setting]—it covers procedural use both in and out of the ICU.” (*Id.*) Sandoz’s argument, however, is completely undermined by FDA’s holding and Hospira’s unequivocal admission that the original and revised use codes are limited to the intensive care setting. (AR 813; *see* AR 90.) Accordingly, Sandoz’s argument is dead on arrival.

IV. ANY INJUNCTION AGAINST FDA IS UNWARRANTED AND INAPPROPRIATE HERE

Hospira is not entitled to any injunction, permanent or preliminary.¹¹ As Par and Mylan have already made clear, the relevant facts and law do not allow Hospira to obtain a preliminary injunction here. (*See* D.I. 39-1, 71, 97-1.) For similar reasons, Hospira’s attempt to secure any permanent injunction must fail. *See Bethesda Softworks, L.L.C. v. Interplay Entm’t Corp.*, 452 F. App’x 351, 354–55 (4th Cir. 2011) (“Despite the differences between preliminary and

¹⁰ Because FDA applied no new “rule” here, Hospira’s reliance on *Morton v. Ruiz*, 415 U.S. 199, 231–36 (1974) is misplaced.

¹¹ Given the nature of this proceeding, wherein summary judgment on the merits is being combined with the request for a preliminary injunction, the preliminary injunction comes into play only if the Court denies both Plaintiffs and Defendants’ cross-motions for summary judgment. In that scenario, the case would go forward, and the Court would need to decide whether it would go forward with or without the injunctive relief requested by Hospira.

permanent injunctive relief, the same equitable principles undergird courts’ authority in each posture.”); *see also Amoco Prod. Co. v. Vill. of Gambell, Alaska*, 480 U.S. 531, 546 n.12 (1987) (“The standard for a preliminary injunction is essentially the same as for a permanent injunction with the exception that the plaintiff must show a likelihood of success on the merits rather than actual success.”).

Here, permanent injunction is appropriate only if Hospira demonstrates: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). Hospira cannot, and its arguments to the contrary are unavailing.

A. Plaintiffs have not suffered or will suffer any irreparable harm

1. Hospira has not demonstrated any irreparable harm

Hospira claims it has suffered “loss of customers, financial loss, loss of market share, and loss of its exclusivity rights.” (D.I. 101-1 at 36.) Regardless of the spin Hospira places on these alleged losses, Hospira’s “harm” here is purely economic, and by no means irreparable. “It is . . . well settled that economic loss does not, in and of itself, constitute irreparable harm.” *Wisc. Gas Co. v. F.E.R.C.*, 758 F.2d 669, 674 (D.C. Cir. 1985); *cf. Fed. Leasing, Inc. v. Underwriters at Lloyd’s*, 650 F.2d 495, 500 (4th Cir. 1981) (finding irreparable injury only when economic losses threatened the very existence of the business). The pure economic nature of Hospira’s alleged losses is underscored by Hospira’s own argument that it has “no recovery of *monetary damages* from FDA for its losses.” (D.I. 101-1 at 36 (emphasis added).) Here, Hospira fails to articulate any non-economic and irreparable harm it will suffer and, for this reason alone, Hospira is not entitled to any injunctive relief. Additionally, these economic harms Hospira has alleged it will

suffer are highly speculative, and do not justify any injunction. *See Virginia Carolina Tools, Inc. v. Int'l Tool Supply, Inc.*, 984 F.2d 113, 120 (4th Cir. 1993) (upholding district court finding that “highly speculative and largely economic injuries did not constitute irreparable harm”); *Mike’s Train House, Inc. v. Broadway Ltd. Imports, LLC*, 708 F. Supp. 2d 527, 532 (D. Md. 2010) (“Mere speculation about possible market share losses is insufficient evidence of irreparable harm.”).

Unable to demonstrate any irreparable harm, Hospira mischaracterizes the record. Despite its allegations, FDA did not confirm that “Hospira’s harm is irreparable at the hearing on August 19.” (D.I. 101-1 at 37.) Hospira’s carefully selected portion from the August 19 Hearing Transcript is misleading; when read in the appropriate context, it is clear that FDA stated only that it could not recall Par’s and Mylan’s products, that it does not “have the ability to go to one of the ANDA holders and say we need you to recall all [their products] right now.” (Hr’g Tr. 48:11–14, Aug. 19, 2014 (D.I. 21).) As the record demonstrates, FDA did not concede that Hospira would be irreparably harmed. Instead, FDA agrees with both Par and Mylan that Hospira has not suffered and will not suffer any irreparable harm. (*See* D.I. 92-1 at 37–39.)

Finally, Hospira’s argument that it “has no remedy at law . . . for the loss that it was denied its procedural rights under the APA” is equally unavailing. (*See* D.I. 101-1 at 37–38.) As Par, Mylan, and FDA made abundantly clear, FDA did not violate the APA here by improperly engaging in rulemaking. It is also unclear what Hospira’s alleges that it has lost here. Assuming, without conceding, that Hospira’s argument that FDA’s actions did not satisfy the notice-and-comment rulemaking requirements pursuant to the APA, Hospira did not suffer any loss as a result because it received notice from FDA (see AR 1–3) and it submitted comments to FDA. (*See, e.g.*, AR 88–103.) Even if Hospira did suffer some harm—even though it does not

articulate it—such alleged harm is not irreparable, but can easily be remedied by this Court.

Hospira’s argument, again, lacks merit.¹²

2. Sandoz has not demonstrated any irreparable harm

As for Sandoz, who had challenged the ’867 patent by submitting a Paragraph IV certification, its argument that it too will suffer irreparable harm is flawed. (*See* D.I. 95 at 22–25.) Brushing aside the voluminous (and irrelevant) case law cited in its brief, Sandoz’s argument boils down to its allegation that it will lose “its 180-day statutory exclusivity as the first generic to challenge the dexmedetomidine patents in Hatch-Waxman litigation.” (*Id.* at 22.) But, Sandoz has not lost, and will not lose, this exclusivity.

Par does not dispute that Sandoz, as the first ANDA applicant to challenge the validity of the ’867 patent, is eligible for 180-day market exclusivity.¹³ Sandoz’s exclusivity, however, is not universal – it is effective with respect to only subsequent ANDA applicants who have also challenged the ’867 patent by submitting a Paragraph IV certification. *See* 21 C.F.R. § 314.107(c)(1). In other words, Sandoz’s exclusivity does not prevent FDA from approving Par’s and Mylan’s ANDAs, which contain section viii statements instead of Paragraph IV certifications. Indeed, “section viii applications cannot be delayed by previous applicants awarded exclusivity, because previous filers of section viii statements are not eligible for an exclusivity period.” *Watson Labs., Inc. v. Sebelius*, C.A. No. 12-1344 ABJ, 2012 WL 6968224, at *3 (D.D.C. Oct. 22, 2012); *see Purepac*, 238 F. Supp. 2d at 195 (“FDA may approve a section

¹² Par has repeatedly challenged Hospira’s claim that the FDA’s approval of Par’s ANDA causes it irreparable harm. Separate and distinct from the Court’s determination on the merits, if this Court now (with a more complete record) found that Hospira would not suffer irreparable harm, the Court could dismiss Hospira’s complaint for a lack of subject matter jurisdiction because Hospira failed to exhaust administrative remedies—i.e., they should be forced to file a Citizen’s Petition instead of a district court action.

¹³ Indeed, Sandoz demonstrated that the ’867 patent is invalid. *See* Order & Judgment, *Hospira, Inc. v. Sandoz Inc.*, No. 09-cv-4591 (D.N.J. Apr. 30, 2012), D.I. 376.

viii application immediately.”). Sandoz is not entitled to prevent other generic applicants, whose product labeling does not infringe the ’867 patent, from obtaining FDA approval.

Here, Sandoz made a strategic choice to submit a Paragraph IV certification in its ANDA instead of a section viii statement, and earned its eligibility for exclusivity by challenging and invalidating the ’867 patent. Sandoz will not lose this exclusivity—once its exclusivity period begins, Sandoz will enjoy 180 days of marketing exclusivity, during which period FDA is prohibited from approving any ANDAs containing the same Paragraph IV certification. 21 C.F.R. § 314.107(c)(1). Despite Sandoz’s efforts to muddy the scope of its exclusivity, Sandoz cannot keep ANDA applicants who submitted section viii statements, such as Par and Mylan, off the market. While Sandoz, understandably, wishes to keep additional competitors away from the market, it has not suffered and will not suffer any harm, let alone irreparable harm.

B. The balance of hardships does not favor injunction

Hospira is not the only party who would be harmed by this Court’s decision on whether to issue an injunction. If this Court delays FDA’s approval of Par’s product, Par will suffer tremendously, in addition to the harm it has already suffered thus far. (*See* D.I. 40 at 9–11; D.I. 39-1 at 35–37 (similar situation for Mylan).) Hospira’s alleged hardship is, at best, similar to those Par and Mylan will suffer—the balance of hardships here does not, therefore, favor injunction. *See Serono Labs. Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998); *Mylan Pharms., Inc. v. Thompson*, 207 F. Supp. 2d 476, 485 (N.D. W. Va. 2001). Furthermore, should this Court grant injunctive relief, FDA will be harmed by “the disruption of the FDA’s generic drug program.” *Mylan Pharms.*, 207 F. Supp. 2d at 486.

Hospira’s reliance on *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharmaceuticals Inc.*, 821 F. Supp. 2d 681 (D.N.J. 2011), is misplaced. There, the New Jersey district court concluded that defendants’ harm suffered “were almost entirely preventable and were the result

of its own calculated risk to launch its product pre-judgment” because they launched their product before obtaining a final ruling on the patent-in-suit’s validity, and “should not be permitted to avoid the consequences of this calculated business risk.” *Id.* at 695. Here, there is no such “business risk.” Par did not launch its product at risk—instead, Par launched its product after obtaining FDA approval, free and clear of any risks. Furthermore, Hospira’s allegation that Par knew “full well that litigation would surely follow” is also without merit. (D.I. 101-1 at 38.) Quite the opposite, the section viii statement Par submitted with its ANDA ensures that no litigation would follow. *See Waxman Amicus Br.*, 2011 WL 3947565, at *12 (section viii “is a key feature of the Hatch-Waxman generic approval framework, designed to enable ANDA applicants . . . to circumvent costly, prolonged Paragraph IV litigation that would delay generic competition for years.” (emphasis added)). In any case, Hospira’s argument fails because Par did not take any risks when it launched its product knowing that the ’867 patent is invalid.¹⁴

C. The public interest does not favor injunction

Par agrees with this Court, and Hospira, that the public has an interest in FDA’s compliance with its governing statute. This is precisely why this Court should not grant any injunctive relief against FDA. Injunction is not warranted here, where FDA did not act arbitrarily and capriciously, and will unnecessarily delay the availability of affordable generic drugs in the market. The public “has a well-recognized interest in receiving generic competition to brand-name drugs as soon as possible . . . and a delay in the marketing of the generic drug could easily be against the public interest in reduced prices.” *ViroPharma, Inc. v. Hamburg*, 898 F. Supp. 2d 1, 29 (D.D.C. 2012); *see Mylan Pharms.*, 207 F. Supp. 2d at 488 (“The public

¹⁴ See Order & Judgment, *Hospira, Inc. v. Sandoz Inc.*, No. 09-cv-4591 (D.N.J. April 30, 2012), D.I. 376.

interest favors promoting competition in the pharmaceutical industry which would, hopefully, have the desired effect of providing a market for affordable and attainable drugs.”).

Just as it did before, Hospira again mischaracterizes FDA’s approval process under section viii. (*See* D.I. 101-1 at 38–39.) FDA’s decision to approve Par’s ANDA does not have the consequence of “undermining [the generic approval] process” intended by Congress. (*Id.*) To be sure, Par agrees that Congress intended to have ANDA applicants submit Paragraph IV certifications and engage in litigations before bringing their generic drugs to market, just as Sandoz had done here. But Congress also fully intended to allow ANDA applicants to submit section viii statements where appropriate, and expressly permit “an ANDA to be approved for less than all of the indications for which the listed drug has been approved.” H.R. Rep. No. 98-857, pt.1, 21–22, *reprinted in* 1984 U.S.C.C.A.N. 2647, at 2654–55. Whereas Sandoz chose the former approach, Par chose the latter—both are equally permissible, and serve the goal of the Hatch-Waxman Act, which is “designed to speed the introduction of low-cost generic drugs to market.” *Caraco*, 132 S. Ct. at 1676.

CONCLUSION

For the foregoing reasons, Par respectfully requests the Court grant its motion for summary judgment, and deny Hospira’s motion for summary judgment. The FDA’s decision approving Par’s ANDA is neither contrary to law nor arbitrary and capricious.

/s/ Michael J. Freno

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a copy of the foregoing INTERVENOR-DEFENDANT PAR STERILE PRODUCTS, LLC'S MEMORANDUM IN OPPOSITION TO HOSPIRA'S MOTION FOR SUMMARY JUDGMENT AND ITS MOTION FOR A PRELIMINARY INJUNCTION was on the 3rd day of September, 2014 served on all parties via the Court's ECF System.

/s/ Michael J. Freno

Michael J. Freno